K002562

OCT 1 3 2000

IX. SMDA Information/Summary of Safety and Effectiveness

Submitter's Name, Address and Contact Information

Valeo Corporation

4F-3, 161, Sung-Teh Road, Taipei, Taiwan 110

Contact Name-C.C. Jean, Marketing Manager

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Fax: 886 2 2346 3115

Summary Preparation Date

February 7, 2000

Proprietary Device Name

Pacifier Thermometer Models VT-910F and VT-901C

Common or Usual Name

Pacifier Thermometer

Device Classification Name

Clinical Electronic Thermometer

Predicate Devices

Device Name: Paci-Temp

Manufacturer: Intelligent Product Limited Co.

510(k) Number: K952073

Substantial Equivalence Date: 12/18/95

Device Name: Clinical Electronic Thermometer

Manufacture: Valeo Corp.

510(k) Number: K982140

Substantial Equivalence Date: 12/08/98

Device Description

The Valeo Pacifier Thermometers are reusable digital thermometers with a pacifier sensor.

Intended Use

The Valeo Pacifier Thermometers are intended for use in taking oral temperatures.

Technological Characteristics Summary

Non-Clinical Tests Submitted

The Valeo Pacifier Thermometers have been subjected to the following non-clinical tests:

Drop Test

Calibration Test

Clinical Tests Submitted

There are no clinical test submitted in conjunction with this Premaket Notification.

Conclusions Drawn From Tests

Based on the non-clinical tests conducted on the Valeo Pacifier Thermometers, these devices are substantially equivalent to the Paci-Temp Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 3 2000

Valeo Corporation
C/O Ms. Marian Harding Cochran
General Counsel
Atico International USA, Incorporated
501 South Andrews Avenue
Fort Lauderdale, Florida 33301

Re: K002562
Trade Name: Pacifier Thermometer Models VT-901F, VT901C
Regulatory Class: II
Product Code: FLL
Dated: August 16, 2000
Received: August 17, 2000

Dear Ms. Cochran:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

Ed Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

X. Indications for Use Statement

510(k) Number (if know): _____

Device Name: Pacifier Thermometer

Indication For Use:

The device is used for the measurement of body temperature through a sensor (transducer) together with an Electronic Signal Amplification, Conditioning, digital LCD (display) unit. The device is reusable and measures oral temperature.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002562